

Remarks

Claims 7, 26-29 and 32 are pending in the subject application and currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the indication that the restriction requirement between groups IV and V is withdrawn.

Applicants gratefully acknowledge the Examiner's withdrawal of the objection to the specification, the double patenting rejections and the rejections under 35 U.S.C. § 112, first and second paragraphs, 35 U.S.C. § 102(b), and 35 U.S.C. § 103(a).

Claims 7, 26-29 and 32 are rejected under 35 U.S.C. § 103(a) as obvious over Talley *et al.* (U.S. Patent No. 5,760,068) in view of Rubino *et al.* (1990). The Office Action states that Talley *et al.* disclose substituted benzene sulfonamides including celecoxib for the treatment of inflammation, which is a widely used commercially available drug for pain. The Office Action also indicates that Talley *et al.* do not teach a propylene glycol solvate of celecoxib. In an effort to remedy this deficiency in the teachings of Talley *et al.*, the Office Action argues that Rubino *et al.* teach that sodium salts of sulfonamides can be improved by crystallization in the presence of propylene glycol and that the reference notes that crystal hydrate or solvate formation might play a role in the trends in the solubility data for the sodium salts reported in the present study (citing to the paragraph bridging pages 143-144). Applicants respectfully submit that the combined teachings of Talley *et al.* and Rubino *et al.* fail to render the claimed invention obvious as one skilled in the art would not have had a reasonable expectation of success in forming a solvate as claimed herein.

In particular, it is respectfully submitted that Rubino *et al.* fail to provide the broad teaching asserted in the Office Action. For example, Rubino *et al.* teach that while a few (several) of the compounds tested exhibited improved solubility in mixed solvents, many of the compounds tested in these same mixed solvents exhibited solubilities that were lower (as compared to their solubilities in water; see Abstract, second sentence).

Further, Rubino *et al.* do not teach the formation of a propylene glycol solvate of a sulfonamide (*e.g.*, celecoxib); rather the reference indicates that most of the compounds (solutes) tested formed crystal hydrates and that mixed solvates were formed in few instances (see Abstract, sentence 4). Indeed, Table 1 indicates that all the sulfonamide compounds tested formed crystal

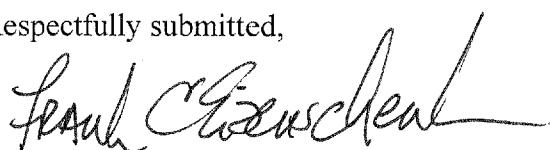
hydrates (see footnote “d” in Table 1). Additionally, the reference indicates that only sodium phenytoin formed a mixed solvate (see page 143, column 2, first full paragraph, last sentence: “As in the case of purely aqueous systems, ***most of the compounds included in the present study formed hydrates, and in the case of phenytoin sodium, evidence of mixed solvates was found*** (see below).” emphasis added). Applicants note that phenytoin does not qualify as a sulfonamide drug (namely phenytoin lacks the SO₂NH₂ radical associated with sulfonamides). Thus, it is respectfully submitted that Rubino *et al.* fail to teach or suggest that one can form propylene glycol solvates of sulfonamide compounds. Therefore, it is respectfully submitted that that one skilled in the art would not have had a reasonable expectation of success in arriving at the claimed sulfonamide (celecoxib) composition (a propylene glycol solvate of celecoxib) in view of the teachings of the cited combination of references and reconsideration and withdrawal of the rejection is respectfully requested.

Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application. Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

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